

REMARKS/ARGUMENTS

Claims 1-10 are currently pending in the above-identified application. Claims 7 and 8 have been allowed by the Examiner. In view of the remarks below, examination and reconsideration of claims 1-6, 9, and 10 are respectfully requested. No amendments to the claims are made in this response.

Rejections under 35 U.S.C. §102:

The Examiner has maintained the rejections of claims 1-6, 9, and 10 as allegedly anticipated by WO 91/00519 (Pourfazaneh-I) under 35 U.S.C. § 102(b) and by corresponding U.S. Patent No. 5,310,656 (Pourfazaneh-II) under 35 U.S.C. § 102(e). The Examiner points to a passage in Pourfazaneh-I and -II that, as stated by the Examiner, "appears to be drawn to a monoclonal antibody that binds to intrinsic factor in the absence of vitamin B12 (mab 5G1) that does not appear to be an antibody that binds to the vitamin B12 binding site, because Pourfazaneh-I appears to distinguish it from antibodies that do bind to the vitamin B12 binding site." Applicants respectfully traverse this rejection.

The passages of Pourfazaneh-I and -II cited by the Examiner pertain to a study in which different IF-specific antibodies were tested for binding to the vitamin B12 binding site of IF or to the IF: vitamin B12 complex. The cited passage describes those antibodies that bound to the B12 binding site of IF (*see* column 10, lines 9-17), and then states that the "remaining antibodies were either specific for IF alone (5G1) or were preferentially specific for the IF: vitamin B12 complex (7E4)." For the reasons below, Applicants respectfully disagree with the Examiner's interpretation of this disclosure as allegedly anticipatory to the present claims.

The present claims recite, *inter alia*, a monoclonal antibody that is "capable of specifically binding to intrinsic factor only in the absence of vitamin B12 and exhibits an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12" (Claim 1).

The Examiner is respectfully directed to column 9, lines 57-66, of Pourfazaneh-II, which describes a study in which different IF-specific antibodies were tested for binding to IF in the presence of vitamin B12 and for inhibition of vitamin B12 binding to IF. The results of this study for four different antibodies, including the 5G1 mAb, are shown in Figure 2. As shown in Figure 2, each antibody was tested for three characteristics:

- (1) binding to IF in the presence of vitamin B12 (left column);
- (2) inhibition of ⁵⁷Co-labelled vitamin B12 binding to IF; (middle column); and
- (3) binding to IF in the absence of vitamin B12 (right column).

In this regard, Applicants specifically direct the Examiner's attention to the IF-binding data shown for the 5G1 mAb. As shown in Figure 2, the binding of mAb 5G1 to IF in the presence of vitamin B12 (left column) was at least equivalent to, or even greater than, the binding of the antibody to IF in the absence of B12 (right column). Thus, the 5G1 mAb of Pourfazaneh-I and -II is not an antibody that specifically binds to intrinsic factor "only in the absence of vitamin B12," as presently recited in the claims.

In view of the above, the 5G1 mAb does not anticipate the present claims. The statement in Pourfazaneh-I and -II specifically cited by the Examiner cannot be interpreted as meaning that the 5G1 mAb binds to IF only in the absence of vitamin B12. In the context of the disclosure, Applicants believe that the vague reference to "binding to IF alone" in the passage cited by the Examiner refers to the ability of mAb 5G1 to bind to IF, but not preferentially to the IF:vitamin B12 complex and not to the B12 binding site. In any case, because the Pourfazaneh references disclose data clearly showing the ability of mAb 5G1 to bind to IF in the presence of B12, the cited references do not anticipate the present claims.

Applicants further note that the Examiner has not shown where the Pourfazaneh references disclose "an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12," as presently recited in the claims.

At least for the reasons set forth above, claims 1-6, 9, and 10 are novel over Pourfazaneh-I and -II under 35 U.S.C. § 102(b) and (e), respectively. Withdrawal of the rejections is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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